PATENT
Attorney Docket No. 06267.0007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13

In re: U.S. Patent 4,670,455

Issued: June 2, 1987

To: Raimo E. Virtanen, Arto J. Karjalainen, Kauko O. A. Kurkela, Antti T. Vähä-Vahe and Outi M. Vainio-Kivinen

Assignee: ORION-YHTYMÄ OY

For: METHOD OF BRINGING ABOUT SEDATION AND/OR ANALGESIA IN A MAMMAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Your applicant, ORION-YHTYMÄ OY, represents that it is the assignee of the entire interest in and to Letters Patent of the United States 4,670,455 granted to Raimo E. Virtanen, Arto J. Karjalainen, Kauko O. A. Kurkela, Antti T. Vähä-Vahe and Outi M. Vainio-Kivinen on the 2nd day of June, 1987 for METHOD OF BRINGING ABOUT SEDATION AND/OR ANALGESIA IN A MAMMAL by virtue of an assignment in favor of ORION-YHTYMÄ OY recorded March 15, 1991, Reel 5635, Frame 0933. By the Power of Attorney enclosed herein (Attachment A), Applicant appoints Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., including Charles E. Van Horn, as attorney for ORION-YHTYMÄ OY with regard to this application for extension of the term of U.S. Patent 4,670,455 and to transact all business in the U.S. Patent and Trademark Office in connection therewith.

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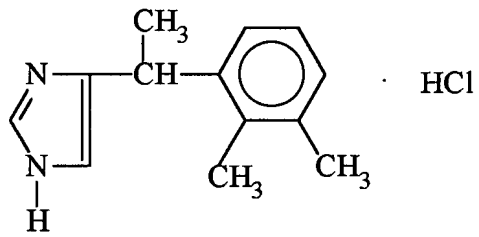
Applicant hereby submits this application for extension of patent term under 35 U.S.C. § 156 by providing the following information required by the rules promulgated by the U.S. Patent and Trademark Office (37 C.F.R. § 1.740). For the convenience of the Patent and Trademark Office, the information contained in this application will be presented in a format which will follow the requirements of Section 1.740 of Title 37 of the Code of Federal Regulations.

Applicant hereby advises the Patent and Trademark Office that an application for extension of the term of U.S. Patent 4,544,664 has been filed also based on the regulatory approval of DOMITOR®. Applicant will elect the patent on which the term extension should be granted in response to a final determination that each patent is eligible for a term extension under 35 U.S.C. § 156. See 37 C.F.R. § 1.785(b).

(1) The approved product DOMITOR® contains medetomidine hydrochloride, chemically described as 4-[(α-methyl)-2,3-dimethylbenzyl]imidazole hydrochloride. Its structural formula is:



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(2) The approved product was subject to regulatory review under the Federal Food, Drug and Cosmetic Act Section 512.

(3) The approved product DOMITOR® received permission for commercial marketing or use under Section 512 of the Federal Food, Drug and Cosmetic Act on March 19, 1996.

(4) The only active ingredient in DOMITOR® is medetomidine hydrochloride, which has not been approved for commercial marketing or use under Section 512 of the Federal Food, Drug and Cosmetic Act prior to the approval of NADA 140-999 by the Food and Drug Administration on March 19, 1996.

(5) This Application for extension of patent term under 35 U.S.C. § 156 is being submitted within the permitted 60 day period pursuant to 37 C.F.R. § 1.720(f), said period which will expire on May 17, 1996.

(6) The complete identification of the patent for which a term extension is being sought is as follows:

Inventors: Raimo E. Virtanen, Arto J. Karjalainen, Kauko O. A. Kurkela, Antti T. Vähä-Vahe and Outi M. Vainio-Kivinen

Patent Number: 4,670,455

Issue Date: June 2, 1987

Expiration Date: December 3, 2005 (20 years from the filing date)

(7) A true copy of the patent is attached. (Attachment B)

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(8) No terminal disclaimer, Certificate of Correction or Re-examination Certificate has been issued. Enclosed are copies of the receipts verifying payment of the maintanance fees in 1990 and 1994 (Attachment C).

(9) U.S. Patent 4,670,455 ('455) claims a method of using DOMITOR®. Claim 1 and Claim 2 of the '455 patent claim a method of use as follows:

1. A method of bringing about sedation and/or analgesia in a small mammal which comprises administering by injection to a small mammal requiring such treatment an effective amount of 4-[(α-methyl)-2,3-dimethylbenzyl]imidazole.

2. A method according to claim 1 in which a sedative effect is produced in a dog or cat by administration by injection of a dosage of 10 to 100 μg/kg.

The claims read on a method of using the approved product DOMITOR®. The active ingredient of DOMITOR®, medetomidine hydrochloride, brings about sedation to a small mammal. Medetomidine hydrochloride is chemically described as 4-[(α-methyl)-2,3-dimethylbenzyl]imidazole hydrochloride. Medetomidine hydrochloride is water soluble and yields medetomidine, the active compound for bringing about sedation to a small mammal.

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(10) The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows:

Investigational New Animal Drug Application (INAD 004-460) for medetomidine hydrochloride was filed March 16, 1985 and became effective on April 8, 1985. Another INAD (INAD 004-884) for medetomidine hydrochloride became effective on December 12, 1986. The filing and effective dates for INAD 004-460 have been used as a basis for the determination of the length of the extension of patent term of U.S. Patent 4,670,455.

New Animal Drug Application (NADA 140-999) for DOMITOR® (medetomidine hydrochloride) was submitted on July 2, 1991.

New Animal Drug Application (NADA 140-999) for DOMITOR® (medetomidine hydrochloride) was approved on March 19, 1996.

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(11) As a brief description of the activities undertaken by Applicant during the applicable regulatory review period, attached hereto is a chronology of the major communications between the Applicant and the FDA from April 8, 1985 to March 19, 1996. (Attachment D)

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(12)(i) Applicant is of the opinion that U.S. Patent 4,670,455 is eligible for extension under 35 U.S.C. § 156 because it satisfies all requirements for such extension as follows:

(a) 35 U.S.C. § 156(a) -- U.S. Patent 4,670,455 claims a method of using the product DOMITOR®.

(b) 35 U.S.C. § 156(a)(1) -- U.S. Patent 4,670,455 has not expired before submission of this application.

(c) 35 U.S.C. § 156(a)(2) -- The term of U.S. Patent 4,670,455 has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3) -- The application for extension is submitted by the owner of record of the patent in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. § 156(d) and rules of the Patent and Trademark Office.

(e) 35 U.S.C. § 156(a)(4) -- The product DOMITOR® has been subjected to a regulatory review period before its commercial marketing or use.

(f) 35 U.S.C. § 156(a)(5)(A) -- The commercial marketing or use of the product DOMITOR® after the regulatory review period is the first permitted commercial marketing or use under the provision of the Federal Food, Drug and Cosmetic Act (i.e., Section 512) under which such regulatory review period occurred.

(g) 35 U.S.C. § 156(c)(4) -- No other patent has been extended for the same regulatory review period for the product DOMITOR®.

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(12)(ii) The length of the extension of patent term of U.S. Patent 4,670,455 claimed by Applicant is 3.00 years. The length of the extension was determined pursuant to 37 C.F.R. § 1.778 as follows:

(a) The regulatory review period under 35 U.S.C. § 156(g)(4)(B) began on April 8, 1985 and ended March 19, 1996, which is total of 3998 days or 10.95 years, which is the sum of (1) and (2) below:

(1) The period of review under 35 U.S.C. § 156(g)(4)(B)(i), the "Testing Period", began on April 8, 1985 and ended on July 2, 1991, which is 6.24 years or 2276 days: and

(2) The period of review under 35 U.S.C. § 156(g)(4)(B)(ii), the "Approval Period", began on July 2, 1991 and ended on March 19, 1996, which is 4.72 years or 1722 days.

(b) The regulatory review period upon which the period of extension is calculated is the entire regulatory review period as determined in sub-paragraph (12)(ii)(a) above (3998 days) less:

(1) The number of days in the regulatory review period which were on or before the date on which the patent issued (June 2, 1987) which is 2.15 years or 786 days; and

(2) The number of days during which applicant did not act with due diligence, which is zero(0) days; and

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(3) One-half the number of days determined in sub-paragraph (12)(ii)(a)(1) after the patent issued (one half of 1490 days) which is 745 days;

(c) The number of days as determined in sub-paragraph (12)(ii)(b) (2467 days or 6.76 years) when added to the original term of the patent (December 3, 2005) would result in the date September 4, 2012;

(d) Fourteen (14) years when added to the date of NADA approval March 19, 1996 would result in the date March 19, 2010;

(e) The earlier date as determined in sub-paragraphs (12)(ii)(c) and (12)(ii)(d) is March 19, 2010;

(f) Since U.S. Patent 4,670,455 issued before November 16, 1988 and a request for an exemption under subsection (j) of section 512 of the Federal Food, Drug, and Cosmetic Act was submitted before November 16, 1988, and the product was approved after that date, the period of extension may not exceed three (3) years. Three (3) years when added to the original expiration date of the patent (December 3, 2005) would result in the date of December 3, 2008.

(g) The earlier date as determined by sub-paragraph (12)(ii)(e) and (12)(ii)(f) is December 3, 2008.

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(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) The prescribed fee for receiving and acting upon this application is attached as a check in the amount of $ 1,060.00. The Commissioner is authorized to charge any additional fees required by this application to Deposit Account No. 06-0916.

(15) All correspondence and inquiries may be directed to the undersigned, whose address, telephone number and fax number are as follows:

Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315
Phone: 202-408-4000
Fax: 202-408-4400

(16) Enclosed is a certification that the application for extension of patent term under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and four (4) copies thereof (Attachment E).

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(17) The requisite declaration pursuant to 37 C.F.R. § 1.740(b) is attached (Attachment F).

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: Charles E. Van Horn
Charles E. Van Horn
Reg. No. 40,266

Dated: 10 May 1996

Attachments:

Power of Attorney (Attachment A)
U.S. Patent 4,670,455 (Attachment B)
Copies of Receipts for Maintanance Fees (Attachment C)
Chronology of Regulatory Review Period (Attachment D)
Certification of Copies of Application Papers (Attachment E)
Declaration pursuant to 37 C.F.R. § 1.740(b) (Attachment F)

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A

PATENT
Attorney Docket No. 06267.0007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent 4,670,455)
)
Issued: June 2, 1987)
)
To: Raimo E. Virtanen, Arto J. Karjalainen,)
Kauko O. A. Kurkela, Antti T. Vähä-Vahe)
and Outi M. Vainio-Kivinen)
)
Assignee: ORION-YHTYMÄ OY)
)
For: Method of bringing about sedation and/or)
analgesia in a mammal)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

POWER OF ATTORNEY

Assignee, ORION-YHTYMÄ OY, being the owner of the above-identified U.S. Letters Patent, hereby grants the power of attorney to **FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Reg. No. 22,540,** Douglas B. Henderson, Reg. No. 20,291; Ford F. Farabow, Jr., Reg. No. 20,630; Arthur S. Garrett, Reg. No. 20,338; Donald R. Dunner, Reg. No. 19,073; Brian G. Brunsvold, Reg. No. 22,593; Tipton D. Jennings, IV, Reg. No. 20,645; Jerry D. Voight, Reg. No. 23,020; Laurence R. Hefter, Reg. No. 20,827; Kenneth E. Payne, Reg. No. 23,098; Herbert H. Mintz, Reg. No. 26,691; C. Larry O'Rourke, Reg. No. 26,014; Albert J. Santorelli, Reg. No. 22,610; Michael C. Elmer, Reg. No. 25,857; Richard H. Smith, Reg. No. 20,609; Stephen L. Peterson, Reg. No. 26,325; John M. Romary, Reg. No. 26,331; Bruce C. Zotter, Reg. No. 27,680; Dennis P. O'Reilley, Reg. No. 27,932; Allen M. Sokal,

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Please send all future correspondence concerning the above matter to Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. at the following address:

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ORION-YHTYMÄ OY

Date: May 7, 1996

Name: Kauko Kurkela Kari Ruottinen
Title: Vice President R&PD Vice President

Date:

Name:

Title:

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United States Patent [19]

Virtanen et al.

[11] **Patent Number: 4,670,455**

[45] **Date of Patent: Jun. 2, 1987**

[54] **METHOD OF BRINGING ABOUT SEDATION AND/OR ANALGESIA IN A MAMMAL**

[75] Inventors: **Raimo E. Virtanen**, Rusko; **Arto J. Karjalainen**; **Kauko O. A. Kurkela**, both of Oulu; **Antti T. Vaha-Vahe**; **Outi M. Vainio-Kivinen**, both of Turku, all of Finland

[73] Assignee: **Farmos-Yhtyma Oy**, Turku, Japan

[21] Appl. No.: **804,197**

[22] Filed: **Dec. 3, 1985**

[30] **Foreign Application Priority Data**

Dec. 4, 1984 [FI] Finland 844786

[51] **Int. Cl.**[4] **A61K 31/415**

[52] **U.S. Cl.** **514/396**

[58] **Field of Search** 514/396

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,544,664 10/1985 Karjalainen 514/396

OTHER PUBLICATIONS

Chem. Abst. 99-38462j (1983).

O. Vainio: "Detomidine HCl–A Novel Imidazole Type Sedative Analgesic, Pharmacologie et Toxicologie Veterinaires, Inra Publ. Paris, 1982, Les Colloques de l'INRA, No. 8.

Primary Examiner—Stanley J. Friedman

Attorney, Agent, or Firm—Armstrong, Nikaido, Marmelstein & Kubovcik

[57] **ABSTRACT**

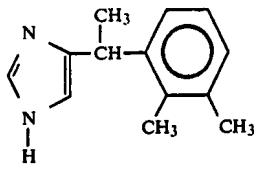
4-[(α-Methyl)-2,3-dimethyl-benzyl]imidazole is useful as a veterinary sedative-analgetic agent, especially in small mammals.

2 Claims, No Drawings

METHOD OF BRINGING ABOUT SEDATION AND/OR ANALGESIA IN A MAMMAL

This invention relates to sedative and analgesic agents useful in the veterinary field.

4-[(α-Methyl)-2,3-dimethyl-benzyl]imidazole of the formula



(I)

has been disclosed in the European Patent Publication No. 72615 as an antihypertensive agent. 4-(2,3-Dimethylbenzyl)-imidazole, or detomidine, is a known sedative and analgesic agent useful in horses and cattle. Detomidine is used in veterinary medicine as a pharmacological restraint to keep the animal sedated before investigation, treatment and difficult medical operations. Even a small surgical operation cannot be carried without the use of a sedative agent. The effect of detomidine in horses and cattle has been described in the literature, e.g. O. Vainio: "Detomidine hydrochloride—a noval imidazole-type sedative-analgesic". Pharmacologie et Toxicologie Veterinaires, INRA Publ. Paris, 1982, Les Colloques de l'INRA, No. 8. There is also a great need for sedative-analgesic agents as pharmacological restraints in the treatment of dogs, cats and other small animals, but no useful effect was, however, observed.

We have now surprisingly found that the above-mentioned detomidine analogue, 4-[(α-methyl)-2,3-dimethylbenzyl]imidazole (compound (I)) is very effective as a sedative-analgesic in the treatment of small animals, especially dogs and cats, but also, e.g., guinea pigs and rabbits. Intramuscular or intravenous administration of this compound at a dose of 10 to 160 μg/kg (in dogs and cats) or 200 to 400 μg/kg (in guinea pigs and rabbits) induces a sedative effect which appears in 2 to 10 minutes after intramuscular (i.m.) administration or in 0.5 to 1 min. after intravenous (i.v.) administration. Both the strength and the duration of the effects are clearly dose dependant. Higher doses have a hypnotic effect during which the animals do not react to external stimuli such as sounds, pain etc. The duration of the effect is about 1 to 4 hours in dogs and 0.5 to 2 hours in cats. Sedation is accompanied by an analgesic effect, especially at higher doses. This compound possesses both a sedative and an analgesic effect, which are clearly superior to those of xylazine, which is a known compound commonly used as sedative in the treatment of small animals. The following test data illustrate the invention. The tests were carried out using six beagle dogs per group. The study was carried out using a cross-over-design. Different doses of compound (I) were given i.m. or i.v.. The reactions observed were compared to those obtained by xylazine.

TABLE 1

	Reaction to sounds									
	compound (I)						xylazine			
dose, μg/kg	40		80		60		1500		3000	
administration	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.
results (number of dogs):										
normal reaction	—	1	—	—	—	—	6	4	2	2
weak reaction	3	—	—	—	1	1	—	2	3	4
no reaction	3	5	6	6	5	5	—	—	1	—
total number of dogs	6	6	6	6	6	6	6	6	6	6

TABLE 2

	Duration of the sedation									
	compound (I)						xylazine			
dose, μg/kg	40		80		160		1500		3000	
administration	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.
duration:										
0–15 min	—	—	—	—	—	—	4	2	2	1
15–30 min	2	2	—	—	—	—	2	4	3	4
30–60 min	4	4	3	4	1	2	—	—	1	1
1–2 h	—	—	3	2	3	3	—	—	—	—
>2 h	—	—	—	—	2	1	—	—	—	—
total number of dogs	6	6	6	6	6	6	6	6	6	6

TABLE 3

	First signs of sedation			
	mean, min		variation, min	
	i.m.	i.v.	i.m.	i.v.
compound (I), 40 μg/kg	5	0.7	3–10	0.5–1
compound (I), 80 μg/kg	3	0.6	2–6	0.5–1
compound (I), 160 μg/kg	2	0.5	2–3	0.5–0.5
xylazine, 1500 μg/kg	4	2	2–8	0.5–10
xylazine, 3000 μg/kg	2	0.5	2–3	0.5–0.5

TABLE 4

	Evaluation of the sedative effect									
	compound (I)						xylazine			
dosage, μg/kg	40		80		160		1500		3000	
administration	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.
no activity	—	—	—	—	—	—	—	—	—	—
some activity	—	1	—	—	—	—	6	6	2	3
good activity	6	5	6	6	6	6	—	—	4	3
total no of dogs	6	6	6	6	6	6	6	6	6	6

TABLE 5

	Evaluation of the analgesic effect									
	compound (I)						xylazine			
dosage, μg/kg	40		80		160		1500		3000	
administration	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.
no activity	—	—	—	—	—	—	—	—	—	—
some activity	1	3	—	—	—	—	6	6	4	5
good activity	5	3	6	6	6	6	—	—	2	1
total no of dogs	6	6	6	6	6	6	6	6	6	6

TABLE 6

	The position of the animal during the maximum effect									
	compound (I)						xylazine			
dosage, μg/kg	40		80		160		1500		3000	
administration	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.	i.m.	i.v.
position:										
standing	—	—	—	—	—	—	1	—	—	—
able to get up easily	—	—	—	—	—	—	4	4	2	2
able to get up with difficulty	3	3	1	—	—	1	1	2	4	4
not able to get up	3	3	5	6	6	5	—	—	—	
total no of dogs	6	6	6	6	6	6	6	6	6	6

We claim:

1. A method of bringing about sedation and/or analgesia in a small mammal which comprises administering by injection to a small mammal requiring such treatment an effective amount of 4-[(α-methyl)-2,3-dinethylbenzyl]imidazole.

2. A method according to claim 1 in which a sedative effect is produced in a dog or cat by administration by injection of a dosage of 10 to 100 μg/kg.

* * * * *

Computer Patent Annuities

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Telephone: 0534 888711
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Telex: 4192137 COPAN G
Cable: COPAN, JERSEY

C

ORION CORP.
ORION-FARMOS PHARMACEUTICALS
PATENT DEPARTMENT
P.O.BOX 65
02101 ESPOO
FINLAND

Our ref: 173654/OFRCPT

Your ref:

Date: 23 NOV 1994

Dear Sir

MLO-1

OFFICIAL RECEIPT / RENEWAL CERTIFICATE

Country Name:	U.S.A.
Type Name:	Patent
Patent No.:	4670455
Reference:	MED-SEDAT
Proprietor:	FARMOS-YHTYMA OY
Base date:	02 JUN 1987
Client no.:	0649228
Annuity:	2

We enclose the official receipt for payment of the annuity indicated above. This document should be kept in a safe place in case proof of renewal is required at any time. If you would like your official receipts stored by CPA in future, please let us know by signing and returning this letter : a fee of £1 for this service will then be added to each future invoice for annuities paid on your account.

Yours faithfully,

Computer Patent Annuities

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

PAYOR NUMBER
000197

75L8/1015
COMPUTER PATENT ANNUITIES
C/O COMPUTER PATENT ANNUITITES, INC.
1111 JEFFERSON DAVIS HIGHWAY
SUITE 514, CRYSTAL GATEWAY NORTH
ARLINGTON, VA 22202

DATE MAILED
10/15/94

MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 10, "status" below. An explanation of the codes appears on the reverse of the Maintenance Fee Statement. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

ITM NBR	PATENT NUMBER	FEE CDE	FEE AMOUNT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT
1	4,670,455	184	1870	----	06/804,197	06/02/87	12/03/85	08	NO	PAID

If the "status" column for a patent number listed above does not indicate "PAID" a code or an asterisk (*) will appear in the "status" column. Where an asterisk (*) appears, the codes are set out below by the related item number. An explanation of the codes indicated in the "status" column and as set out below by the related item number appears on the reverse of the maintenance fee statement.

ITM NBR	ATTY DKT NUMBER
1	P418-566-K85

DIRECT THE RESPONSE TOGETHER WITH ANY QUESTIONS ABOUT THIS NOTICE TO

MAINTENANCE FEE STATEMENT
STATUS CODES AND DEFINITIONS

CODE	DEFINITION
	IN REGARD TO THE MAINTENANCE FEE PAYMENT(S)
F160	The maintenance fee has already been paid. A refund of the payment has been scheduled to be sent to the fee address of record.
F161	The maintenance fee payment will not be accepted because it has been tendered too early. See 37 CFR 1.362. A refund of the payment has been scheduled.
F162	The maintenance fee payment does not properly identify the patent for which payment is to be made in accordance with 37 CFR 1.366(c). Either the U. S. application serial number or the patent number has been omitted. Both numbers are necessary to ensure proper crediting of the maintenance fee to the desired patent.
F163	The maintenance fee payment based upon certificate of mailing procedures is untimely, since it is not in compliance with the requirements of 37 CFR 1.8.
F164	The maintenance fee payment based upon "Express Mail" procedures is untimely since it is not in compliance with the requirements of 37 CFR 1.10.
F165	The maintenance fee and surcharge payment are not accepted because they have been submitted with the payment of fees for other purposes. See 37 CFR 1.366(e). A refund of the payment has been scheduled.
F166	The maintenance fee payment is not accepted because it is not immediately negotiable in the United States for the full payment of the required fee. Payment should be made in U. S. specie, Treasury notes, national bank notes, post office money orders or by certified check. See 37 CFR 1.23. The payment is returned herewith.
F167	The check or deposit account authorization is not accepted because it is unsigned. It is returned herewith.
F168	The payment received or the balance in the deposit account authorized for payment is insufficient to cover payment of the maintenance fee and surcharge, if any. Any payments accepted have been applied in accordance with the provisions of 37 CFR 1.366(e).
F169	The payment is in excess of the amount required. A refund has been scheduled.
	IN REGARD TO THE STATEMENT OF SMALL ENTITY STATUS
E180	A signature to the small entity statement is omitted.
E181	A small entity statement from each joint inventor has not been received.
E182	A small entity statement from the assignee or licensee has not been received.
E183	The requirements for filing as an independent inventor have not been met. See 37 CFR 1.9(c).
E 184	The requirements for filing as a small business concern have not been met. See 37 CFR 1.9(d).
E185	The requirements for filing as a nonprofit organization have not been met. See 37 CFR 1.9(e).
E186	The small entity statement was not verified by an oath or a declaration.

Computer Patent Annuities
PATENT, DESIGN & TRADE MARK RENEWALS WORLD WIDE
TRADE MARK SEARCHING

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INTERNATIONAL PROPERTY DEPT.
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SF-20101 TURKU 10
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7046

208 ACCOUNT 64922

OFFICIAL RECEIPT/RENEWAL CERTIFICATE

WE ENCLOSE THE OFFICIAL RECEIPT FOR THE FOLLOWING PATENT. THIS DOCUMENT SHOULD BE KEPT IN A SAFE PLACE IN CASE PROOF OF RENEWAL IS REQUIRED AT ANY TIME. IF YOU WOULD LIKE YOUR OFFICIAL RECEIPTS KEPT AND STORED HERE IN FUTURE, PLEASE LET US KNOW BY SIGNING AND RETURNING THIS LETTER: A FEE OF £1 FOR THIS SERVICE WOULD THEN BE ADDED TO EACH FUTURE INVOICE FOR ANNUITIES PAID ON YOUR ACCOUNT.

DATE 06 AP[illegible]

COUNTRY	PATENT NO.	DUE DATE	ANNUITY	YOUR REFERENCE / PATENTEE
USA (FULL FEES)	4670455	DEC.02	04	MED-1/AMO/EH FARMOS-YHTYMA OY-804197-03DEC85

USA (FULL FEES)	4670439	DEC.02	4	[illegible]	
USA (FULL FEES)	4670448	DEC.02	4	GLAXO GROUP LTD -465616-10FEB83	490.00
USA (FULL FEES)	4670455	DEC.02	4	FARMOS-YHTYMA OY-804197-03DEC85	490.00
USA (FULL FEES)	4670538	DEC.02	4	CHLOE CHIMIE -832264-21FEB86	490.00
USA (SMALL ENTITY)	4670539	DEC.02	4	BD REGENTS U.TX -635220-27JUL84	245.00
USA (FULL FEES)	4670555	DEC.02	4	UNIROYAL CHEM.CO-725029-19APR85	490.00
USA (FULL FEES)	4670603	DEC.02	4	NOBEL CHEM.AB -779797-24SEP85	490.00
USA (FULL FEES)	4670626	DEC.02	4	RELIANCE COMM -821078-21JAN86	490.00
USA (FULL FEES)	4670642	DEC.02	4	NIPPON KOKAN KK -780085-25SEP85	490.00
USA (FULL FEES)	4670704	DEC.02	4	NIPPONDENSO -872491-10JUN86	490.00

Computer Patent Annuities

PATENT & TRADE MARK RENEWALS WORLD WIDE
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INSTRUCTIONS

COMPUTER PATENT ANNUITIES
C/O COMPUTER PATENT ANNUITIES INC.
SUITE 514, CRYSTAL GATEWAY NORTH
1111 JEFFERSON DAVIS HIGHWAY
ARLINGTON VA 22202

PAYOR NUMBER 000197

herewith submits payment of the following maintenance fees.
Please stamp and return the enclosed copy of these instructions
as acknowledgement of receipt of this payment.

Account no. 08890 Page 8

Date 19/10/90

	Patent no.	Due Date	Year	Patentee	Serial No.	Filing Date	Fee $
USA (FULL FEES)	4670439	DEC.02	4	BOEHRINGER MANN.	-755496-	16JUL85	490.00
USA (FULL FEES)	4670448	DEC.02	4	GLAXO GROUP LTD	-465616-	10FEB83	490.00
USA (FULL FEES)	4670455	DEC.02	4	FARMOS-YHTYMA OY	-804197-	03DEC85	490.00
USA (FULL FEES)	4670538	DEC.02	4	CHLOE CHIMIE	-832264-	21FEB86	490.00
USA (SMALL ENTITY)	4670539	DEC.02	4	RD REGENTS U.TX	-635220-	27JUL84	245.00
USA (FULL FEES)	4670555	DEC.02	4	UNIROYAL CHEM.CO	-725029-	19APR85	490.00
USA (FULL FEES)	4670603	DEC.02	4	NOBEL CHEM.AB	-779797-	24SEP85	490.00
USA (FULL FEES)	4670626	DEC.02	4	RELIANCE COMM	-821078-	21JAN86	490.00
USA (FULL FEES)	4670642	DEC.02	4	NIPPON KOKAN KK	-780085-	25SEP85	490.00
USA (FULL FEES)	4670704	DEC.02	4	NIPPONDENSO	-872491-	10JUN86	490.00

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Chronology of Events on DOMITOR® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

DATE	EVENT
April 8, 1985	S. O'Hara of FDA/CVM Document Control Section wrote to Dr. W. Jöchle acknowledging March 16, 1985, submission and assigning INAD number 004-460 for DOMITOR® in dogs to the file.
April 9, 1985	Dr. T. Shotwell of Shotwell & Carr, Inc., Regulatory Consultant for Orion FARMOS, submitted proposed protocol for efficacy study for FDA review.
August 27, 1985	Dr. M. Larkins of FDA/CVM provided comments on the efficacy protocol submitted April 9, 1985.
September 18, 1986	INAD conference with FDA/CVM held in Rockville, MD regarding studies on the drug.
October 29, 1986	P. Weldy of Animed, Inc., submitted a letter from FARMOS authorizing Animed to act on behalf of FARMOS, requesting expedited review status on the file, and documenting the chemical and pharmacological properties of the drug.
December 12, 1986	Dr. M. Norcross of FDA/CVM wrote to P. Weldy assigning INAD number 004-884 to the file, denying expedited review status and advising that comments on the October 29, 1986 submission would be sent when agency review is complete.
January 9, 1987	Dr. M. Larkins of FDA/CVM provided comments on the October 29, 1986

	submission and requested protocols for pivotal safety and efficacy studies plus additional data on safety of the drug.
January 20, 1987	Original submission of the MF005-150 to the FDA
February 17, 1987	Development of the protocol for a pivotal dose response study began.
May 15, 1987	INAD conference with FDA/CVM held in Rockville, MD regarding dose response studies.
May 18, 1987	Minutes of May 15, 1987 meeting submitted to FDA/CVM for comment.
August 31, 1987	Revisions on Incremental Dose Response Study protocol submitted to FDA/CVM for comment.
September 18, 1987	Dose Response Study in dogs was initiated. Completed, October 23, 1987.
October 23, 1987	Dose Response Study in dogs was completed. Initiated September 18, 1987.
October 27, 1987	Protocol for clinical trials in dogs was submitted to FDA/CVM for comment.
November 24, 1987	Dr. M. Larkins of FDA/CVM provided additional recommendations for modifying the protocol on dose response studies.
December 17, 1987	Protocol for Target Animal Safety study was submitted to FDA/CVM for comment.
December 18, 1987	Summary of intramuscular injection Target Animal Safety study completed in Finland was submitted for FDA/CVM comment.

Chronology of Events on DOMITOR® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

January 11, 1988	Studies on pharmacology, pharmacokinetics, efficacy and safety were submitted to support second request for assignment of expedited review status to the file.
January 20, 1988	Dr. M. Larkins of FDA/CVM provided agency comments on the October 27, 1987 protocol for clinical trials.
March 2, 1988	Dr. R. Carnevale of FDA/CVM responded to the submission of January 11, 1988 and denied expedited review status to the file.
March 18, 1988	Dr. B. Griffith of FDA/CVM provided agency comments on the December 17, 1987 Target Animal Safety study protocol and requested submission of the full Target Animal Safety study done in Finland.
April 1988	Animed ceased to serve as US Agent for Orion FARMOS
May 17, 1988	Dr. W. Jöchle, Wolfgang Jöchle Associates, Inc. (WJA) re-instated as the U.S. Agent for Orion FARMOS for INAD 004-884.
May 25, 1988	First draft of dose response study report was received from Dr. R. Hamlin.
January 25, 1989	Dr. W. Jöchle (WJA) and Mark Shepard (Shotwell & Carr) visited Dr. R. Hamlin for raw data review and classifications regarding the dose response study.
March 13, 1989	Dr. W. Jöchle submitted report for a pivotal Dose Titration Study and a Target Animal Safety study. He also requested a conference with FDA/CVM to discuss the studies.

Chronology of Events on Domitor® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

April 26, 1989	Dr. W. Jöchle (WJA) submitted to CVM/FDA protocols for efficacy and safety studies for review and comments.
May 11, 1989	Conference held with FDA/CVM representatives to discuss dose titration, target animal safety, and clinical studies.
September 15, 1989	Conference held jointly with FDA/CVM representatives, FARMOS representatives, and Norden Laboratories (SmithKline Beecham Animal Health) representatives to discuss dose determination results and protocols for Target Animal Safety and Clinical Trials with Domitor in dogs. Agreement was reached on the optimum dose for subsequent studies to support NADA approval.
September 22, 1989	Dr. W. Jöchle (WJA) submitted to CVM/FDA minutes of the September 15, 1989 meeting.
November 2, 1989	Dr. W. Jöchle (WJA) submitted to CVM/FDA information on the corrected dosing charts for DOMITOR®.
November 3, 1989	Controlled study to compare the effectiveness of DOMITOR® to INNOVAR® was initiated. Completed March 26, 1990.
November 7, 1989	Pivotal Target Animal Safety study in dogs via intravenous administration was initiated. Completed May 3, 1990.
November 18, 1989	Dr. M.K. Larkins, CVM/FDA, called Dr. W. Jöchle (WJA) to advise that clinical studies could commence since protocols were acceptable.

Chronology of Events on DOMITOR® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

December 1, 1989	First controlled multicenter clinical trial to evaluate the sedative and analgesic effects of DOMITOR® as compared to xylazine was initiated. Completed January 4, 1991.
January 17, 1990	Corroborative study of cardiovascular effects of DOMITOR® in dogs was initiated. Completed November 30, 1990.
January 23, 1990	Second controlled multicenter clinical trial to evaluate the sedative and analgesic effects of DOMITOR® as compared to xylazine was initiated. Completed December 31, 1990.
March 26, 1990	Controlled study to compare the effectiveness of DOMITOR® to INNOVAR® was completed. Initiated November 3, 1989.
March 31, 1990	Third controlled multicenter clinical trial to evaluate the sedative and analgesic effects of DOMITOR® as compared to xylazine was initiated. Completed December 21, 1990
March 31, 1990	Controlled clinical trial to compare DOMITOR® to xylazine in dental care was initiated. Completed December 21, 1990.
April 9, 1990	FDA/CVM provided Orion FARMOS with a copy of the agency's minutes of the meeting held May 11, 1989.
April 20, 1990	Norden Laboratories (SmithKline Beecham Animal Health) initiated study to compare dose response with DOMITOR® administered on a body surface basis with the response when administered on a body weight basis. Completed May 16, 1990.

Chronology of Events on Domitor® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

May 3, 1990	Pivotal Target Animal Safety study in dogs via intravenous administration was completed. Initiated November 7, 1989.
May 16, 1990	Norden Laboratories (SmithKline Beecham Animal Health) completed a study to compare dose response with DOMITOR® administered on a body surface basis with the response when administered on a body weight basis. Initiated April 20, 1990.
July 16, 1990	Corroborative study was initiated on the effects of DOMITOR® when administered to heartworm positive dogs. Completed September 17, 1990.
July 17, 1990	Corroborative study of safety in puppies was initiated. Completed July 26, 1990.
July 26, 1990	Corroborative study of safety in puppies was completed. Initiated July 17, 1990.
August 3, 1990	Dr. Bob Griffith, CVM/FDA confirmed in a letter the correctness of the minutes for the September 15, 1989 meeting submitted by Dr. Jöchle; provided CVM's own minutes for this meeting, and confirmed the dose.
August 3, 1990	Dr. Bob Griffith, CVM/FDA, responded to the submission of April 26, 1989, and provided comments to the protocols for safety and efficacy studies.
August 13, 1990	Dr. Bob Griffith, CVM/FDA requested additional information from Dr. Jöchle about drug shipments to investigators.
August 22, 1990	Dr. W. Jöchle (WJA) provided CVM/FDA with additional information on drug shipments as requested.

Chronology of Events on DOMITOR® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

September 17, 1990	Corroborative study of safety in heartworm positive dogs was completed. Initiated July 16, 1990.
September 28, 1990	Amendment to the INAD was filed by FARMOS to provide analytical and chemical documentation for DOMITOR®.
November 30, 1990	Corroborative study of cardiovascular effects of DOMITOR® in dogs was completed. Initiated January 17, 1990.
December 21, 1990	Third controlled clinical trial on the sedative and analgesic effects of DOMITOR® compared to xylazine was completed. Initiated March 31, 1990.
December 21, 1990	Controlled clinical trial to compare DOMITOR® to xylazine in dental care was completed. Initiated March 31, 1990.
December 31, 1990	Second controlled multicenter clinical trial to evaluate the sedative and analgesic effects of DOMITOR® as compared to xylazine was completed. Initiated January 23, 1990.
January 4, 1991	First controlled multicenter clinical trials to evaluate the sedative and analgesic effects of DOMITOR® as compared to xylazine was completed. Initiated December 1, 1989.
January 10, 1991	Newly edited updated MF005-150 submitted.
January 21, 1991	Updated pages to MF005-150 concerning the expiry date of the substance sent to FDA.
February 11, 1991	Acknowledgement of receipt of the updated MF005-150 requested from FDA.

Chronology of Events on Domitor® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

March 27, 1991	Acknowledgement of receipt of updated MF005-150 and request to provide more information on the deficiencies noted by FDA.
May 15, 1991	Acknowledgement of receipt of the updated MF005-150 and request to provide more information on stability by FDA.
July 2, 1991	Completed NADA submitted to FDA/CVM for agency approval.
October 7, 1991	Patent certification submitted to FDA/CVM as an Amendment to the NADA.
October 18, 1991	Response to the deficiencies noted on March 27, 1991.
January 7, 1992	Dr. Bob Griffith of FDA/CVM reported the agency review of the file was incomplete and should require 3 to 5 more weeks.
January 17, 1992	Telephone call from Dr. Jöchle to Dr. M.K. Larkins who advised that the response letter could be expected in January '92.
January 21, 1992	Acknowledgement of receipt of the response dated October 18, 1991 and request for further clarifications by FDA.
February 17, 1992	Telephone call from Dr. Jöchle to Dr. M.K. Larkins who advised that reports from outside consultants have been delayed; hence, FDA/CVM's response letter will be available in March.
March 25, 1992	Response to the deficiencies of January 21, 1992
April 2, 1992	Telephone call from Dr. Griffith of FDA/CVM: He has no news; all parties

	involved in CVM are busy on this NADA. Sponsor should provide data on efficacy and safety on computer diskettes to speed up review.
April 14, 1992	Telephone call from Dr. B. Griffith and Dr. A. Yancy of FDA/CVM requested the sponsor provide the FOI Summary on computer diskettes.
April 20, 1992	Freedom of Information Summary on electronic diskettes was submitted to FDA/CVM as requested by Dr. Bob Griffith.
April 30, 1992	Itemization of adverse reactions that occurred since March 1991 was submitted to FDA/CVM as requested by Dr. Bob Griffith. See also June 15, 1992.
May 18-19, 1992	FARMOS manufacturing facilities in Oulu were inspected by FDA in a pre-approval inspection. A form-483 was issued.
May 20-22, 1992	FARMOS manufacturing facilities in Turku were inspected by FDA in a pre-approval inspection. A form -483 was issued.
June 5, 1992	Response to the form-483 issued on May 19, 1992 was sent.
June 9, 1992	Telephone call from Dr. Jöchle to Dr. M.K. Larkins: FDA's consultants had not finalized their reports; Dr. Jöchle should call again in a week.
June 11, 1992	Response to the form-483 issued on May 22, 1992 was sent.
June 15, 1992	Dr. W. Jöchle (WJA) provided CVM/FDA with adverse reaction reports, nationally and internationally.

Chronology of Events on Domitor® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

June 19, 1992	Telephone call from Dr. Jöchle to Dr. A. Yancy: Consultant's report(s) was(were) received. Dr. Yancy inquired about the formulation used by FARMOS for the I.M. target species safety study.
June 23, 1992	Dr. W. Jöchle (WJA) provided CVM/FDA (Dr. Yancy) with information regarding the formulation used by FARMOS in the I.M. target species safety study.
June 25, 1992	Receipt of the responses of March 25, 1992 acknowledged by FDA and statement received that FDA has no further comments regarding the submission.
July 1, 1992	Dr. M.K. Larkins advised Dr. W. Jöchle that the response letter may be available within 5 days.
July 17, 1992	Dr. M. Larkins of FDA/CVM reported agency review of the NADA file was complete and the response letters for veterinary medical review and chemistry review were in preparation.
August 18, 1992	Dr. W. Jöchle (WJA) provided CVM/FDA with an additional adverse reaction report from abroad (UK).
October 7, 1992	First official FDA/CVM response to the NADA: Dr. L.D. Rollins of FDA/CVM wrote to Dr. Jöchle to report completion of the review of the NADA and to identify incomplete portions of the application.
October 15, 1992	Follow-up letter ot inform about the status of the corrective actions stated in the response of June 11, 1992, was sent.
October 21, 1992	MF005-420 submitted.

Chronology of Events on DOMITOR® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

October 27, 1992	Conference held with representatives of FDA/CVM and FARMOS. Dr. Jöchle and Dr. Shotwell discussed responses to FDA/CVM to complete the application.
October 29, 1992	MF005-436 submitted.
November 16, 1992	Dr. Jöchle submitted minutes of October 27, 1992 meeting to FDA/CVM.
March 3, 1993	CVM response to October 29, 1992 submission of MF005-436.
March 8, 1993	Dr. L.D. Rollins of FDA/CVM wrote to Dr. Jöchle to provide corrections and clarifications to the minutes of the October 27, 1992 meeting.
March 12, 1993	Amendment to NADA filed by Dr. W. Jöchle to respond to all FDA/CVM comments and concerns about approval of the application.
May 26, 1993	MF005-436 section I, II and III submitted.
August 11, 1993	Meeting between CVM and Orion.
August 23, 1993	W. Jöchle submits sponsor's minutes of August 11, 1993 meeting to CVM.
August 31, 1993	CVM response to May 26, 1993 amendment to MF005-436.
September 3, 1993	W. Jöchle sends corrections to minutes of August 11, 1993 meeting to L. Rollins.
October 20, 1993	MF005-436 annual update submitted.

Chronology of Events on Domitor® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

January 28, 1994	CVM responds to original NADA filing of July 2, 1991, and to NADA amendment of March 12, 1993.
May 5, 1994	MF005-150 update submitted.
May 10, 1994	MF005-436 update submitted.
May 20, 1994	MF005-436 amended.
May 26, 1994	MF005-436 volumes I and II submitted.
July 7, 1994	Submission of MF005-150 update acknowledged by FDA and further information concerning residual solvents requested.
August 19, 1994	Response to the request of July 7, 1994.
October 20, 1994	MF005-436 annual update submitted.
December 6, 1994	Receipt of the response dated August 19, 1994 acknowledged by FDA and commented that they have no adverse comment regarding the submission.
June 16, 1995	W. Jöchle submits amendment to NADA to provide for change in manufacturing site from Turku to Espoo, to provide official notification of sponsor name change, and to respond to issues in CVM letter dated January 28, 1994.
August 9, 1995	W. Jöchle submits amendment to NADA to correct erroneous dates in June 16, 1995 amendment.
October 26, 1995	Proposal regarding MF005-436 type V submitted for approval by FDA.
October 27, 1995	Teleconference between W. Jöchle and Drs. L. Rollins and S. Woods, and D.

Chronology of Events on DOMITOR® (medetomidine HCl)
INAD 004-460 and 004-884
NADA 140-999

	Vandeck to discuss status of CVM chemistry review of NADA.
November 3, 1995	Teleconference from Drs. L. Rollins and E. Reese of CVM to Dr. W. Jöchle to request revisions to FOI Summary and labeling. Fax on same date from Dr. E. Reese to Dr. W. Jöchle describing requested label changes.
December 19, 1995	Call from Dr. E. Reese, CVM/FDA to Dr. W. Jöchle to discuss concerns with FOI Summary: Table 18 does not jibe with text.
January 12, 1996	Revised FOI Table 18 and diskette with the entire revised FOI submitted to Dr. E. Reese, CVM/FDA by Dr. W. Jöchle.
February 3, 1996	Revised labeling submitted to Dr. E. Reese by Dr. W. Jöchle in response to request of November 3, 1995.
February 23, 1996	FDA approved the proposal submitted on October 26, 1995.
February 26, 1996	Telephone request from Dr. E. Reese to Dr. T. Shotwell to request additional label changes.
March 1, 1996	Revised labeling sent to Dr. E. Reese by Dr. W. Jöchle in response to request of February 26, 1996.
March 19, 1996	Final approval letter issued by CVM making approval of Domitor effective on this date.

E

PATENT
Attorney Docket No. 06267.0007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent 4,670,455)
)
Issued: June 2, 1987)
)
To: Raimo E. Virtanen, Arto J. Karjalainen,)
Kauko O. A. Kurkela, Antti T. Vähä-Vahe)
and Outi M. Vainio-Kivinen)
)
Assignee: ORION-YHTYMÄ OY)
)
For: METHOD OF BRINGING ABOUT SEDATION AND/OR)
ANALGESIA IN A MAMMAL)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CERTIFICATION

I, CHARLES E. VAN HORN do hereby certify that this accompanying application for extension of the term of U.S. Patent 4,670,455 under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and four (4) copies thereof.

Respectfully submitted,

Charles E. Van Horn

Charles E. Van Horn
Reg. No. 40,266

Dated: 10 May 1996

LAW OFFICES
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& DUNNER, L.L.P.
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202-408-4000

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PATENT
Attorney Docket No. 06267.0007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent 4,670,455)
)
Issued: June 2, 1987)
)
To: Raimo E. Virtanen, Arto J. Karjalainen,)
Kauko O. A. Kurkela, Antti T. Vähä-Vahe)
and Outi M. Vainio-Kivinen)
)
Assignee: ORION-YHTYMÄ OY)
)
For: METHOD OF BRINGING ABOUT SEDATION AND/OR)
ANALGESIA IN A MAMMAL)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION ACCOMPANYING
APPLICATION UNDER 35 U.S.C. § 156 FOR EXTENSION OF PATENT TERM

I, CHARLES E. VAN HORN do hereby declare:

I am a patent attorney authorized to practice before the United States Patent and Trademark Office and I have been appointed as attorney by the Patent Assignee, ORION-YHTYMÄ OY, with regard to this application for extension of the term of U.S. Patent 4,670,455 and to transact all business in the U.S. Patent and Trademark Office in connection therewith.

I have reviewed and understand the contents of the accompanying application being submitted pursuant to 37 C.F.R. § 1.740.

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I believe that the patent is subject to extension pursuant to § 1.710.

I believe that an extension of the length claimed is justified under 35 U.S.C. § 156 and applicable regulations.

I believe the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

Respectfully submitted,

Charles E. Van Horn

Charles E. Van Horn
Reg. No. 40,266

Dated: 10 May 1996

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